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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,923	09/15/2003	Peter M. Bonutti	2500DV2CN2DV3CN2	2728

7590 10/25/2004

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EXAMINER

THALER, MICHAEL H

ART UNIT PAPER NUMBER

3731

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/662,923	<b>Applicant(s)</b> BONUTTI, PETER M.	
	<b>Examiner</b> Michael Thaler	<b>Art Unit</b> 3731	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 August 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 2-5 and 7-12 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-5 and 7-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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Claims 2, 5 and 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crittenden et al. (5,102,390) in view of Kontos et al. (5,180,367). Crittenden et al. disclose first tubular member 12 having an open proximal end, first inflatable member 26, second tubular member 10 having an open proximal end and an open distal end defining a bore 16 therethrough (col. 5, lines 8-11) and second inflatable member 20. Crittenden et al. fail to disclose the first tubular member 12 having an open distal end (since guidewire 44 plugs the distal end of tubing as indicated in col. 7, lines 22-23). However, Kontos et al. teach that the tubular member of the inner, pilot balloon can have an open distal end so that it can slidably receive the guidewire instead of being fixed to the guidewire (col. 8, lines 8-19). This arrangement has the self-evident advantage of enabling the position of the tubular member to be adjusted relative to the guidewire. It would have been obvious to make the distal end of first tubular member 12 Crittenden et al. open so that it can slidably receive a guidewire so that it too would have this advantage. The slidable guidewire is considered to be the surgical instrument referred to in the claim.

Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crittenden et al. (5,102,390) in view of Kontos et al. (5,180,367) as applied to claim 2 above, and

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further in view of Evard et al. (4,981,478). Crittenden et al. fail to disclose an inner member defining an annular space with the first tubular member. However, Evard et al. teach that a balloon catheter can be constructed with an inner tubular member 13, outer tubular member 11 with an annular space therebetween (col. 4, lines 19-30). This arrangement has the advantage of enabling inflation fluid to pass through the annular space and a guidewire to slidably pass through the inner tubular member while maintaining a small profile. It would have been obvious to so construct the Crittenden et al. first tubular member so that it too would have this advantage.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crittenden et al. (5,102,390) in view of Kontos et al. (5,180,367) as applied to claim 2 above, and further in view of Mecca (4,690,140). The distal end of first tubular member 12 Crittenden et al., as modified above to be open so that it can slidably receive a guidewire (the claimed surgical instrument) would inherently be capable of receiving an endoscope or laparoscopic instrument since an endoscope or laparoscopic instrument can be as small in diameter as a guidewire. Mecca is cited to support this assertion since it discloses a very thin endoscopic guide member 1 which is broadly an endoscope since it allows viewing into the area (col. 2,

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lines 10-14 and col. 6, lines 1-9). Note that the surgical instrument itself is not part of the claimed combination.

Applicant's arguments filed August 18, 2004 have been fully considered but they are not persuasive. Although the guidewire of Kontos et al. is very thin, it is still a "surgical instrument", as broadly claimed. Dictionary.com defines "instrument" as "An implement used to facilitate work". A guidewire is clearly an implement used to facilitate work. In any event, the surgical instrument itself is not being claimed as part of the claimed combination.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981. The examiner can normally be reached Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (703)308-2154. The fax phone number for the organization where this application or proceeding is assigned is (703)872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

mht  
10/21/04



MICHAEL THALER  
PRIMARY EXAMINER  
ART UNIT 3731